Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

VA/DoD clinical practice guideline for the management of pregnancy.

Bibliographic Source(s)

Management of Pregnancy Work Group. VA/DoD clinical practice guideline for the management of pregnancy. Version 3.0. Washington (DC): Department of Veterans Affairs, Department of Defense; 2018 Mar. 147 p. [237 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Department of Veteran Affairs, Department of Defense. VA/DoD clinical practice guideline for management of pregnancy. Washington (DC): Department of Veteran Affairs, Department of Defense; 2009. 163 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition

YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▮▮	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	**Specific and Unambiguous Articulation of Recommendations**
▮▮▮▮▮	**External Review**
▮▮▮▮▮	**Updating**

Recommendations

Major Recommendations

Note from the Department of Veterans Affairs and the Department of Defense (VA/DoD) and the National Guideline Clearinghouse (NGC): The recommendations for the management of pregnancy are organized into 4 sections with 1 algorithm. The accompanying recommendations are provided below. See the original guideline document for the algorithms and evidence tables associated with selected recommendations, including level and quality of evidence, strength of recommendation, and supporting evidence citations.

The strength of recommendation grading (Strong For, Weak For, Strong Against, Weak Against) and recommendation categories (Reviewed, Not reviewed, New-added, New-replaced, Not changed, Amended, Deleted) are defined at the end of the "Major Recommendations" field.

Care Throughout Pregnancy

A. Routine Care During Pregnancy

The Work Group suggests offering a group model of prenatal care as an acceptable alternative to individual provider appointments. (Weak For; Not Reviewed, Amended)

The Work Group recommends that all healthy, pregnant women without known contraindications

participate in regular mild to moderate exercise sessions, three or more times per week. (Strong For; Reviewed, Amended)

The Work Group suggests that women with uncomplicated pregnancies continue a standard work schedule throughout their pregnancy. (Weak For; Not Reviewed, Amended)

B. Nutrition

The Work Group recommends folic acid (at least 400 micrograms daily) to be taken starting one month before conception and continued throughout pregnancy and breastfeeding. (Strong For; Not Reviewed, Amended)

C. Screening

The Work Group recommends screening for use of tobacco, alcohol, illicit drugs, and unauthorized use of prescription medication because their use is common and can result in adverse outcomes. For women who screen positive, they recommend additional evaluation and treatment (see the NGC summary of the VA/DoD Clinical practice guideline for the management of substance use disorders and the VA/DoD Clinical practice guideline for the management of tobacco use). (Strong For; Reviewed, Amended)

The Work Group recommends screening for depression using a standardized tool such as the Edinburgh Postnatal Depression Scale or the 9-item Patient Health Questionnaire periodically during pregnancy and postpartum. (Strong For; Reviewed, New-replaced)

D. Education

The Work Group recommends breastfeeding education, assessment, and support to all pregnant women and their families at the first visit and throughout the pregnancy and postpartum period using open-ended questions such as "What do you know about breastfeeding?" (Strong For; Reviewed, New-replaced)

One-Time Interventions

A. Screening and Diagnostic Testing

The Work Group suggests making prenatal diagnostic testing for aneuploidy available to all pregnant women. (Weak For; Reviewed, New-replaced)

The Work Group recommends offering prenatal screening for aneuploidy and the most common clinically significant genetic disorders to all pregnant women. When aneuploidy screening is desired, cell-free fetal DNA screening should be considered; however, screening test selection should be individualized and take into account the patient's age, baseline aneuploidy risk, and test performance for a given condition. (Strong For; Reviewed, New-replaced)

The Work Group suggests the two-step process (one-hour oral glucose challenge test followed by three-hour oral glucose tolerance test) to screen for gestational diabetes mellitus at 24 to 28 weeks gestation for all pregnant women. (Weak For; Reviewed, New-replaced)

B. Imaging

The Work Group recommends first-trimester ultrasound to establish or confirm the gestational age and estimated birth date, identify multiple pregnancies, and confirm the presence of cardiac activity. (Strong For; Reviewed, New-replaced)

For pregnant women who present after the first trimester, the Work Group suggests performing a dating and anatomical ultrasound at the earliest opportunity, preferably prior to 22 weeks.

C. Preparing for Delivery

The Work Group recommends offering scheduled delivery to women who reach 41 weeks and 0/7 days undelivered. Antepartum fetal testing should begin at 41 weeks and 0/7 days if not scheduled for delivery. (Strong For; Reviewed, Amended)

D. Postpartum Care

For pregnant women who have a past or current history of gestational diabetes mellitus, hypertension, or preeclampsia, the Work Group recommends documenting the reproductive history and making women aware of the increased lifetime risks of cardiovascular disease and/or diabetes. (Strong For; Reviewed, New-added)

Referral

The Work Group suggests that pregnant women with an unexplained elevation of maternal serum alpha-fetoprotein be evaluated and counseled by a qualified obstetric provider due to increased risk for adverse perinatal outcomes. (Weak For; Not Reviewed, Amended)
The Work Group recommends against routine screening for preterm delivery using the fetal fibronectin test in asymptomatic women. (Strong Against; Not Reviewed, Amended)
The Work Group recommends considering the use of fetal fibronectin testing as a part of the evaluation strategy in women between 24 and 34 6/7 weeks gestation with signs and symptoms of preterm labor, particularly in facilities where the result might affect management of delivery. (Strong For; Not Reviewed, Amended)

Special Considerations

A. High Risk for Preeclampsia

In women at risk of preeclampsia, the Work Group recommends low dose (e.g., 100-150 mg daily) aspirin therapy initiated at or before 16 weeks gestation. (Strong For; Reviewed, New-added)

B. High Risk for Preterm Delivery

The Work Group recommends antenatal progesterone therapy in consultation with an advanced prenatal care provider (e.g., obstetrician or maternal-fetal medicine) for women at high risk for recurrent preterm delivery and who meet the generally accepted inclusion criteria. (Strong For; Not Reviewed, Amended)

C. Over 44 Years of Age

The Work Group suggests offering women greater than 44 years of age planned delivery at 38 weeks gestational age to reduce the risk of stillbirth. (Weak For; Reviewed, New-added)

D. History of Bariatric Surgery

The Work Group suggests that women who have undergone bariatric surgery should be evaluated for nutritional deficiencies and need for nutritional supplementation where indicated (e.g., vitamin B12, folate, iron, calcium). (Weak For; Reviewed, New-replaced)
For pregnant women who have undergone bariatric surgery, there is insufficient evidence to recommend for or against the routine supplementation of vitamins A, D, E, or K. (N/A; Reviewed, New-replaced)
The Work Group suggests that pregnant women with a history of gastric bypass surgery be evaluated by a surgeon with bariatric expertise. (Weak For; Reviewed, Amended)

Definitions

The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

Occasionally, instances may occur when the Work Group feels there is insufficient evidence to make a recommendation for or against a particular therapy or preventive measure. This can occur when there is an absence of studies on a particular topic that met evidence review inclusion criteria, studies included in the evidence review report conflicting results, or studies included in the evidence review report inconclusive results regarding the desirable and undesirable outcomes.

Using these elements, the grade of each recommendation is presented as part of a continuum:

Strong For (or "The Work Group recommends offering this option …")
Weak For (or "The Work Group suggests offering this option …")
No recommendation for or against (or "There is insufficient evidence …")
Weak Against (or "The Work Group suggests not offering this option …")
Strong Against (or "The Work Group recommends against offering this option …")

Note that weak (For or Against) recommendations may also be termed "Conditional," "Discretionary," or "Qualified." Recommendations may be conditional based upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented. Recommendations may be at the discretion of the patient and clinician or they may be qualified with an explanation about the issues that would lead decisions to vary.

Recommendation Categories and Definitions

A set of recommendation categories was adapted from those used by the United Kingdom National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated from the 2009 Pregnancy clinical practice guideline (CPG).

Evidence Reviewed*	Recommendation Category*	Definition*
Reviewed	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed based on review of the evidence
Not reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been reviewed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed because it was deemed out of scope for the updated CPG

*Adapted from the NICE guideline manual (2012) and Garcia et al. (2014).

Clinical Algorithm(s)

An algorithm designed to inform providers of the recommended interventions and appropriate timing of each of the interventions for women during pregnancy and in the postpartum period is provided in the

original guideline document.

Scope

Disease/Condition(s)

- Pregnancy
- Complications of pregnancy

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Medical Genetics

Nursing

Obstetrics and Gynecology

Preventive Medicine

Psychiatry

Psychology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To provide healthcare providers with a framework by which to evaluate, treat, and manage the

individual needs and preferences of pregnant women, thereby leading to improved clinical outcomes
- To assist healthcare providers in all aspects of care for a pregnant woman
- To improve patients' health and well-being by guiding health care providers who are taking care of pregnant women along the management pathways that are supported by evidence

Target Population

Pregnant women who are eligible for care in the Department of Veterans Affairs (VA) and Department of Defense (DoD) healthcare delivery systems. It includes Veterans as well as deployed and non-deployed Active Duty Service, Guard, and Reserve Members and their dependents.

Note: Regardless of setting, any patient in the healthcare system should ideally have access to the interventions that are recommended in this guideline after taking into consideration the patient's specific circumstances.

Interventions and Practices Considered

1. Group model of prenatal care
2. Mild to moderate exercise
3. Continuation of standard work schedule
4. Folic acid
5. Screening for use of tobacco, alcohol, illicit drugs, and unauthorized use of prescription medication
6. Screening for depression using a standardized tool
7. Breastfeeding education, assessment, and support
8. Prenatal diagnostic testing for aneuploidy
9. Prenatal screening for aneuploidy and common genetic disorders
10. Screening for gestational diabetes (one-hour and three-hour oral glucose tolerance tests)
11. First-trimester ultrasound
12. Offering scheduled delivery at 41 weeks and 0/7 days
13. Antepartum fetal testing at 41 weeks
14. Educating women with a history of gestational diabetes mellitus, hypertension, or preeclampsia about the increased lifetime risks of cardiovascular disease and/or diabetes
15. Evaluation and counseling for pregnant women with an unexplained elevation of maternal serum alpha-fetoprotein
16. Fetal fibronectin testing for women with signs and symptoms of preterm labor
17. Low dose aspirin therapy for women at high risk for preeclampsia
18. Antenatal progesterone therapy for women at high risk for recurrent preterm delivery
19. Offering planned delivery at 38 weeks for women greater than 44 years of age
20. Evaluation for nutritional deficiencies and need for nutritional supplementation for women who have undergone bariatric surgery
21. Evaluation by a bariatric surgeon for women who have undergone bariatric surgery

Note: The following was considered but not recommended: routine screening for preterm delivery using the fetal fibronectin test in asymptomatic women. There was insufficient evidence to recommend for or against routine supplementation of vitamins A, D, E, or K for women who have undergone bariatric surgery.

Major Outcomes Considered

- Sensitivity and specificity of screening tests
- Risk factors for preterm birth
- Effectiveness of timely comprehensive screening
- Effectiveness of counseling and education

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Developing the Scope and Key Questions

The clinical practice guideline (CPG) Champions, along with the Work Group, were tasked with identifying key questions (KQs) to guide the systematic review (SR) of the literature on pregnancy. These questions, which were developed in consultation with the Lewin team, addressed clinical topics of the highest priority for the Department of Veterans Affairs (VA) and Department of Defense (DoD) populations. The KQs follow the population, intervention, comparison, outcome, timing and setting (PICOTS) framework for evidence questions, as established by the Agency for Healthcare Research and Quality (AHRQ). Table A-1 in the original guideline document provides a brief overview of the PICOTS typology.

The Champions, Work Group, and evidence review team carried out several iterations of this process, each time narrowing the scope of the CPG and the literature review by prioritizing the topics of interest. Due to resource constraints, all developed KQs were not able to be included in the systematic evidence review. Thus, the Champions and Work Group determined which questions were of highest priority, and those were included in the review. Table A-2 in the original guideline document contains the final set of KQs used to guide the SR for this CPG.

Conducting the Systematic Review

Based on the decisions made by the Champions and Work Group members regarding the scope, the KQs, and the PICOTS statements, the Lewin Team produced a systematic review protocol prior to conducting the review. The protocol was reviewed and approved by the Champions and Work Group members. It described in detail the final set of KQs, the methodology to be used during the systematic review process, and the inclusion/exclusion criteria to be applied to each potential study, including, but not limited to, study type, sample size, and PICOTS criteria.

Extensive literature searches identified 6,863 citations potentially addressing the KQs of interest to this evidence review. Of those, 3,276 were excluded upon title review for clearly not meeting inclusion criteria (e.g., not pertinent to the topic, not published in English, published prior to study inclusion publication date, or not a full-length article). Overall, 3,554 abstracts were reviewed with 2,677 of those being excluded for the following reasons: not an SR or an accepted study design (see the General Criteria for Inclusion in Systematic Review and Key Question Specific Criteria), did not address a KQ of interest to this review, did not report on an outcome of interest, or published outside cut-off publication dates. A total of 910 full-length articles were reviewed. Of those, 601 were excluded at a first pass review for the following: not addressing a KQ of interest, not enrolling the population of interest, not meeting inclusion criteria for study design, not meeting inclusion criteria for any KQ, or being a duplicate. A total of 309 full-length articles were thought to address one or more KQs and were further reviewed. Of these, 239 were ultimately excluded. Reasons for their exclusion are presented in Figure A-1 in the original guideline document.

General Criteria for Inclusion in Systematic Review

- Studies or SRs published on or after January 1, 2008 to February 4, 2017, except as noted below. If multiple SRs addressed a KQ, the most recent and/or comprehensive review was included. SRs were supplemented with clinical studies published subsequent to the SR.
  - An updated search for KQ 9 was done on March 1, 2017, in which pregnancy and synonyms were not included in the search, as it was determined that the original search parameters were too restrictive. The Work Group identified one additional systematic review that addressed KQ 9, which was published later than the original date cut-off, and was added to the evidence base for that question.

At the face-to-face meeting it was determined that retrospective studies potentially were needed to more fully address KQ 10. Updated searches were conducted up to May 18, 2017. The Work Group identified two additional studies that addressed KQ 10 that were added to the evidence base for that question.

English language publication.

Publication must have been a full study or SR; abstracts alone were not included. Similarly, letters, editorials, and other publications that were not full-length clinical studies were not accepted as evidence.

Intervention studies needed to have a treatment or management style and have been a prospective, randomized controlled trial (RCT) with an independent control group, unless otherwise noted (see Key Question Specific Criteria below). Crossover trials were not included. The ideal diagnostic study compares clinical outcomes after diagnostic technology evaluation versus clinical evaluation, or compares clinical outcomes linked to different diagnostic technologies. However, non-comparative diagnostic studies that reported a change in management strategy or patient outcomes (e.g., evidence of organic based disease patterns) were included.

Study must have enrolled at least 20 patients (10 per study group) unless otherwise noted (see Key Question Specific Criteria below).

Study must have reported on an outcome of interest. Studies must have enrolled a patient population in which at least 80% of patients were pregnant at the time of enrollment. If the percentage was less than 80%, then data must have been reported separately for the patient subgroup.

Key Question Specific Criteria

For KQs 1, 4, and 6, acceptable study designs included SRs of acceptable study designs, RCTs, and diagnostic cohort studies.

For KQ 4, studies examining cost-effectiveness must have been prospective comparisons or cohort studies looking at diagnostic performance of one or more tests and a cost effectiveness analysis. Modeling studies using previously published or retrospectively analyzed data (e.g., from patient registries and/or Medicare payer reports) or studies using published diagnostic performance data to simulate the cost effectiveness of testing in a hypothetical cohort (i.e., no actual patient data incorporated into the model) were excluded.

For KQs 2, 7, and 9, acceptable study designs included SRs of acceptable study designs, RCTs (if available), large prospective (100 patients per arm) and retrospective (200 patients per arm) cohort studies. Cohort studies must have performed multivariate analyses of the prognostic factors of interest on patient outcomes.

For KQ 2, studies looking at incidental use of aspirin were not included.

For KQs 3, 8, and 10 acceptable study designs included SRs of RCTs and/or individual RCTs.

For KQ 5, SRs of acceptable study designs and RCTs were prioritized. If insufficient evidence was available to address the KQ, then large prospective (100 patients per arm) and retrospective (200 patients per arm) cohort studies were considered. Cohort studies must have performed multivariate analyses of the prognostic factors of interest on patient outcomes.

If insufficient evidence was available to address a KQ, then large prospective (100 patients per arm) non-RCTs were considered. Retrospective analyses were not included.

Literature Search Strategy

Bibliographic Database Information

Cochrane Database of Systematic Reviews (Cochrane Reviews): January 1, 2008 to February 4, 2017 (Wiley)

Cochrane Central Register of Controlled Trials: January 1, 2008 to February 4, 2017 (Wiley)

Database of Abstracts of Reviews of Effects: January 1, 2008 to February 4, 2017 (Wiley)

EMBASE (Excerpta Medica): January 1, 2008 to February 4, 2017 (Elsevier)

Health Technology Assessment Database (HTA): January 1, 2008 to February 4, 2017 (Wiley)

MEDLINE/PreMEDLINE: January 1, 2008 to February 4, 2017 (Elsevier)

PsycINFO: January 1, 2008 to February 4, 2017(OvidSP)
PubMed (In-process and Publisher records): January 1, 2008 to February 4, 2017 (National Library of Medicine)

Additional information on the search strategies, including topic-specific search terms and search strategies, can be found in Appendix F in the original guideline document.

Number of Source Documents

Overall, 70 studies addressed one or more of the KQs and were considered as evidence in the review. Table A-2 in the original guideline document indicates the number of studies that addressed each of the questions. See Figure A-1 in the original guideline document for a study flow diagram.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence Rating and Definitions*

High quality — Further research is very unlikely to change confidence in the estimate of effect.
Moderate quality — Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low quality — Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very low quality — Any estimate of effect is very uncertain.

*Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y., Alonso-Coello, P., Schünemann, H. J. & the GRADE Working Group. (2008). GRADE; An emerging consensus on rating quality of evidence and strength of recommendations. *BMJ, 336*, 924-926.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Abstraction and Data Management

For each study included in the review, the Work Group abstracted the following study level details: country, purpose, and quality rating. For previous systematic reviews, they reported the search strategy used, study selection criteria, and overall information about the evidence base, including number of included studies and overall patients enrolled. For intervention studies and previous systematic reviews, the Work Group also abstracted data about characteristics of the included patients and treatments assessed. Finally, for all studies, they abstracted data on the findings for the outcomes of interest for this review.

Assessment of Individual Study Quality (Methodological Risk of Bias of Individual Studies)

Risk-of-bias (or study quality) of individual diagnostic, observational, and interventional studies was assessed using the U.S. Preventive Services Task Force (USPSTF) method. Each study is assigned a rating

of Good, Fair, or Poor based on sets of criteria that vary depending on study design. Detailed lists of criteria and definitions of Good, Fair, or Poor ratings for different study designs appear in Appendix VII of the USPSTF procedure manual . USPSTF does not provide criteria for rating prognostic studies; these studies were assessed using the Quality in Prognosis Studies (QUIPS) tool . The QUIPS tool assesses risk of bias in the domains of study participation, study attrition, prognostic factor measurement, confounding measurement and account, outcome measurement, and analysis and reporting. Each prognostic study is assigned a rating of High, Moderate, or Low risk of bias based on how each study addresses potential confounders in each domain.

Data Synthesis

The Work Group used a narrative approach to synthesizing the evidence for all the key questions. As indicated in the VA/DoD Guidelines for Guidelines document, the first line of evidence was previous systematic reviews. For questions in which a previous review was available, individual studies that met this review's inclusion criteria were used to supplement or update the previous review. For questions where multiple systematic reviews with similar arrays of included individual studies are available, the Work Group chose the most comprehensive (in terms of the number of high-quality cited studies) and/or recent systematic review for the evidence synthesis in order to avoid multiple ratings of a similar evidence base. Additional systematic reviews not contributing to the overall grading of evidence may be included in narrative summaries of their findings, particularly if they contain a small number of unique, but high quality, individual studies. For questions for which no previous review was available, the Work Group summarized the overall findings for the outcomes of interest of the studies that addressed a key question.

Assessing the Overall Quality of the Body of Evidence for an Outcome

The overall quality of the body of evidence supporting the findings for the outcomes of interest in the evidence report was assessed using the GRADE system. The GRADE system primarily involves consideration of the following factors: overall study quality (or overall risk of bias or study limitations), consistency of evidence, directness of evidence, and precision of evidence. Given time and resources, other factors such as publication bias may also be considered. The definitions of the factors listed above are provided in Table 4 in the systematic review (see the "Availability of Companion Documents" field). For more information on the GRADE system go to the GRADE working group Web site .

The GRADE system rates the overall quality of the evidence as high, moderate, low, and very low (see the "Rating Scheme for the Strength of the Evidence" field). For instance, a body of evidence that consists of RCTs automatically starts with a rating of high quality. This rating can be downgraded if some of the RCTs have serious flaws such as lack of blinding of outcome assessors, not reporting concealment of allocation, or high dropout rate. Similarly, the quality can be downgraded or further downgraded if inconsistencies of findings are present or if there is a lack of precision surrounding an outcome's effect size.

Assessing Applicability

When describing the evidence base addressing a key question, the Work Group discussed aspects of the included studies, such as inclusion/exclusion criteria, characteristics of included patients, and characteristics of the treatments assessed, that may make the overall findings of the studies more or less applicable to the population, treatments, or outcomes of interest to this review.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Methods

The current document is an update to the 2009 *Department of Veterans Affairs/Department of Defense (VA/DoD) Pregnancy Clinical Practice Guideline (CPG)*. The methodology used in developing the 2018 CPG follows the *Guideline for Guidelines*, an internal document of the VA and DoD Evidence-Based Practice Work Group (EBPWG). The VA/DoD *Guideline for Guidelines* can be downloaded from http://www.healthquality.va.gov/policy/index.asp (see also the "Availability of Companion Documents" field). This document provides information regarding the process of developing guidelines, including the identification and assembly of the Guideline Champions (Champions) and other subject matter experts from within the VA and DoD, known as the Work Group and, ultimately, the development and submission of a new or updated Pregnancy CPG.

The Champions and Work Group for this CPG were charged with developing evidence-based clinical practice recommendations and writing and publishing a guideline document to be used by providers within the VA/DoD healthcare systems as well as those within the community who treat individuals within the VA and DoD. Specifically, the Champions and Work Group members for this guideline were responsible for identifying the key questions (KQs) of the most clinical relevance, importance, and interest for the management of pregnant women. The Champions and the Work Group also provided direction on inclusion and exclusion criteria for the evidence review and assessed the level and quality of the evidence. The amount of new scientific evidence that had accumulated since the previous version of the CPG was also taken into consideration in the identification of the KQs. In addition, the Champions assisted in:

- Identifying appropriate disciplines of individuals to be included as part of the Work Group
- Directing and coordinating the Work Group
- Participating throughout the guideline development and review processes

The VA Office of Quality, Safety and Value, in collaboration with the Office of Evidence Based Practice, U.S. Army Medical Command, the proponent for CPGs for the DoD, identified four clinical leaders, Heather Able, MSN, RNC and Alicia Christy, MD, MHSCR, FACOG from the VA and COL Lisa Foglia, MD, FACOG and Lt Col Barton Staat, MD, FACOG from the DoD, as Champions for the 2018 CPG.

The Lewin Team, including The Lewin Group, Duty First Consulting, ECRI Institute, and Sigma Health Consulting, LLC, was contracted by the VA and DoD to support the development of this CPG and conduct the evidence review. The first conference call was held in October 2016, with participation from the contracting officer's representative (COR), leaders from the VA Office of Quality, Safety and Value and the DoD Office of Evidence Based Practice, and the Champions. During this call, participants discussed the scope of the guideline initiative, the roles and responsibilities of the Champions, the project timeline, and the approach for developing and prioritizing specific research questions on which to base a systematic review (SR) about the management of pregnancy. The group also identified a list of clinical specialties and areas of expertise that are important and relevant to the management of pregnancy, from which Work Group members were recruited. The specialties and clinical areas of interest included: breastfeeding/lactation, care coordination, cardiology, clinical psychology, dietetics, family medicine, gynecology, internal medicine, mental health, midwifery, nursing, nutrition, obstetrics, psychiatry, women's health, and physical therapy.

The guideline development process for the 2018 CPG update consisted of the following steps:

- Formulating and prioritizing key questions (KQs)
- Convening patient focus groups
- Conducting the systematic evidence review
- Convening a face-to-face meeting with the CPG Champions and Work Group members
- Drafting and submitting a final CPG on the management of pregnancy to the VA/DoD EBPWG

Appendix A in the original guideline document provides a detailed description of each of these tasks.

Convening the Face-to-face Meeting

In consultation with the contracting officer's representative (COR), the Champions, and the Work Group,

the Lewin Team convened a three and one half day face-to-face meeting of the CPG Champions and Work Group members on May 16–19, 2017. These experts were gathered to develop and draft the clinical recommendations for an update to the 2009 Pregnancy CPG. Lewin presented findings from the evidence review in order to facilitate and inform the process.

Under the direction of the Champions, the Work Group members were charged with interpreting the results of the evidence review and were asked to categorize and carry forward recommendations from the 2009 Pregnancy CPG, modifying the recommendations as necessary. The members also developed new clinical practice recommendations not presented in the 2009 Pregnancy CPG based on the 2017 evidence review. The subject matter experts were divided into two smaller subgroups at this meeting.

As the Work Group members drafted clinical practice recommendations, they also assigned a grade for each recommendation based on a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) and U.S. Preventive Services Task Force (USPSTF) methodology. Each recommendation was graded by assessing the quality of the overall evidence base, the associated benefits and harms, the variation in values and preferences, and other implications of the recommendation.

In addition to developing recommendations during the face-to-face meeting, the Work Group members also revised the 2009 Pregnancy CPG algorithms to reflect the new and amended recommendations. They discussed the available evidence as well as changes in clinical practice since 2009, as necessary, to update the algorithms.

Grading Recommendations

The Champion and Work Group used the GRADE system to assess the quality of the evidence base and assign a strength for each recommendation. The GRADE system uses the following four domains to assess the strength of each recommendation:

- Balance of desirable and undesirable outcomes
- Confidence in the quality of the evidence
- Patient or provider values and preferences
- Other implications, as appropriate, e.g.,: ï‚i
  - Resource use
  - Equity
  - Acceptability
  - Feasibility
  - Subgroup considerations

The framework in Table A-4 in the original guideline document was used by the Work Group to guide discussions on each domain.

The strength of a recommendation is defined as the extent to which one can be confident that the desirable effects of an intervention outweigh its undesirable effects and is based on the framework in Table A-4, which combines the four domains. GRADE methodology does not allow for recommendations to be made based on expert opinion alone. While strong recommendations are usually based on high or moderate confidence in the estimates of effect (quality of the evidence) there may be instances where strong recommendations are warranted even when the quality of evidence is low. In these types of instances where the balance of desirable and undesirable outcomes and values and preferences played large roles in determining the strength of a recommendation, this is explained in the discussion section for the recommendation.

The GRADE of a recommendation is based on the following elements:

- Four decision domains used to determine the strength and direction (described above)
- Relative strength (Strong or Weak)
- Direction (For or Against)

Reconciling 2009 Clinical Practice Guideline Recommendations

Evidence-based CPGs should be current, which typically requires revisions of previous guidelines based on new evidence, or as scheduled and subject to time-based expirations. For example, the USPSTF has a process for refining or otherwise updating its recommendations pertaining to preventive services. Further, the inclusion criteria for the National Guideline Clearinghouse specify that a guideline must have been developed, reviewed, or revised within the past five years.

The Pregnancy Guideline Work Group focused largely on developing new and updated recommendations based on the evidence review conducted for the priority areas addressed by the KQs. In addition to those new and updated recommendations, the Work Group considered, without complete review of the relevant evidence, the current applicability of other recommendations that were included in the previous 2009 Pregnancy CPG, subject to evolving practice in today's environment.

A set of recommendation categories was adapted from those used by the National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which older recommendations could have been updated. In brief, the categories took into account whether or not the evidence that related to a recommendation was systematically reviewed, the degree to which the recommendation was modified, and the degree to which a recommendation is relevant in the current care environment and within the scope of the CPG. Additional information regarding these categories and their definitions can be found in Recommendation Categorization section in the original guideline document. The categories for the recommendations included in the 2018 version of the guideline can be found in the "Major Recommendations" field. The categories for the recommendations carried forward from the 2009 Pregnancy CPG are noted in Appendix D in the original guideline document.

The CPG Work Group recognized the need to accommodate the transition in evidence rating systems from the 2009 Pregnancy CPG to the current CPG. In order to report the strength of all recommendations using a consistent format (i.e., the GRADE system) the CPG Work Group converted the USPSTF strengths of the recommendation accompanying the carryover recommendations from the 2009 guideline to the GRADE system. As such, the CPG Work Group considered the strength of the evidence cited for each recommendation in the 2009 Pregnancy CPG as well as the intervention's harms and benefits, values and preferences, and other implications, where possible. The CPG Work Group referred to the available evidence as summarized in the body of the 2009 Pregnancy CPG and did not systematically re-assess the evidence. In some instances, relevant peer-reviewed literature published since the 2009 Pregnancy CPG was considered along with the original evidence base for the specific recommendation. Where such newer literature was considered when converting the strength of the recommendation from the USPSTF to the GRADE system, it is referenced in the discussion that follows the corresponding recommendation, as well as in Appendix C in the original guideline document.

The CPG Work Group recognizes that, while there are sometimes practical reasons for incorporating findings from a previous SR, previous recommendations, or recent peer-reviewed publications into an updated CPG, doing so does not involve an original, comprehensive SR and, therefore, may introduce bias.

Drafting and Submitting the Final Clinical Practice Guideline

Following the face-to-face meeting, the Champions and Work Group members were given writing assignments to craft discussion sections to support each of the new recommendations and/or to update discussion sections from the 2009 Pregnancy CPG to support the amended "carried forward" recommendations. The Work Group also considered tables, appendices, and other sections from the 2009 Pregnancy CPG for inclusion in the update. During this time, the Champions and Work Group also made additional revisions to the algorithms, as necessary.

Rating Scheme for the Strength of the Recommendations

The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

Occasionally, instances may occur when the Work Group feels there is insufficient evidence to make a recommendation for or against a particular therapy or preventive measure. This can occur when there is an absence of studies on a particular topic that met evidence review inclusion criteria, studies included in the evidence review report conflicting results, or studies included in the evidence review report inconclusive results regarding the desirable and undesirable outcomes.

Using these elements, the grade of each recommendation is presented as part of a continuum:

Strong For (or "The Work Group recommends offering this option …")
Weak For (or "The Work Group suggests offering this option …")
No recommendation for or against (or "There is insufficient evidence …")
Weak Against (or "The Work Group suggests not offering this option …")
Strong Against (or "The Work Group recommends against offering this option …")

Note that weak (For or Against) recommendations may also be termed "Conditional," "Discretionary," or "Qualified." Recommendations may be conditional based upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented. Recommendations may be at the discretion of the patient and clinician or they may be qualified with an explanation about the issues that would lead decisions to vary.

Recommendation Categories and Definitions

A set of recommendation categories was adapted from those used by the United Kingdom National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated from the 2009 Pregnancy clinical practice guideline (CPG).

Evidence Reviewed*	Recommendation Category*	Definition*
Reviewed	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed based on review of the evidence
Not reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been reviewed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed because it was deemed out of scope for the updated CPG

*Adapted from the NICE guideline manual (2012) and Garcia et al. (2014).

See Appendix A in the original guideline document for further details on categorization.

Cost Analysis

Published cost analyses were reviewed for Key Question 4.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

After developing the initial draft of the updated clinical practice guideline (CPG), an iterative review process was used to solicit feedback on and make revisions to the CPG. Once they were developed, the first two drafts of the CPG were posted on a wiki Web site for a period of 14 to 20 business days for internal review and comment by the Work Group. All feedback submitted during each review period was reviewed and discussed by the Work Group and appropriate revisions were made to the CPG.

Draft 3 of the CPG was made available for peer review and comment. This process is described in the "Peer Review Process" section in the original guideline document. After revisions were made based on the feedback received during the peer review and comment period, the Champions presented the CPG to the Evidence Based Practice Work Group (EBPWG) for their approval. Changes were made based on feedback from the EBPWG and the guideline was finalized. The final 2018 Pregnancy CPG was submitted to the EBPWG in March 2018.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Table A-2 in the original guideline document indicates the number and type of studies that addressed each of the questions.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The expected outcome of successful implementation of this guideline is to:

Assess the condition of the mother and baby and determine the best management method in collaboration with the mother and, when possible and desired, other family and caregivers
Optimize the mother and baby's health outcomes and improve quality of life
Minimize preventable complications and morbidity
Emphasize the use of patient-centered care (PCC)

Refer to the "Discussion" sections following each recommendation in the original guideline document for information on the balance between benefits and harms for specific recommendations.

Potential Harms

- Pregnant women may note an increase in uterine cramping with moderate exercise or activity; this is rarely problematic, as long as the cramping ceases with termination of activity.
- Potential harms of screening for depression include time spent on screening and discomfort with screening questions.
- The potential harms of prenatal diagnostic testing for aneuploidy include the small, but known, risk of pregnancy loss, which is about 1/455 (0.22%) for chorionic villus sampling (CVS) and about 1/900 (0.1%) for amniocentesis.
- Risks of aneuploidy screening include false positive and negative results, potential pregnancy loss if patients subsequently pursue invasive diagnostic testing, and maternal anxiety from testing.
- Harms associated with testing for gestational diabetes include treatment with insulin for those who would not necessarily develop these complications, as well as the time and expense of both counseling and treatment.
- One potential harm of referral maternal serum alpha-fetoprotein (MSAFP) testing is that the subgroup of women who will experience complications cannot be predicted. Further, knowledge of the test results and increased surveillance may heighten anxiety, and place the pregnant woman at risk for increased, and potentially unnecessary, interventions.
- The benefits of taking low dose aspirin outweigh the harms of potential placental abruption, postpartum hemorrhage, or fetal harms such as intracranial bleeding and congenital anomalies.

Refer to the "Discussion" sections following each recommendation in the original guideline document for information on the balance between benefits and harms for specific recommendations.

Contraindications

Contraindications

- The varicella vaccine is contraindicated during pregnancy.
- Due to concerns about possible teratogenicity, the measles/mumps/rubella (MMR) vaccination is not recommended during pregnancy.
- Obstetric contraindications to aerobic exercise include incompetent cervix or cerclage, multiple gestation, at risk of preterm labor, persistent second or third trimester bleeding, placenta previa after 26 weeks gestation, preterm labor during the current pregnancy, and ruptured membranes. Maternal contraindications to aerobic exercise include hemodynamically significant heart disease and restrictive lung disease.
- According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) guideline for clinical application of laparoscopic bariatric surgery, while evidence to support absolute contraindications for bariatric surgery is lacking, expert consensus states that women who are pregnant or who are considering pregnancy in the next 18 to 24 months should not be considered candidates for bariatric surgery.

Qualifying Statements

Qualifying Statements

- The Department of Veterans Affairs and the Department of Defense guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be

construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

- This clinical practice guideline (CPG) is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.
- Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.
- These guidelines are not intended to represent Department of Veterans Affairs or TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at www.tricare.mil or by contacting your regional TRICARE Managed Care Support Contractor.

Implementation of the Guideline

Description of Implementation Strategy

Implementation

This clinical practice guideline (CPG) and algorithm are designed to be adapted by individual healthcare providers with consideration of local needs and resources. The algorithm serves as a tool to prompt providers to consider key decision points in the course of an episode of care.

Although this CPG represents the recommended practice on the date of its publication, medical practice is evolving and this evolution requires continuous updating based on published information. New technology and more research will improve patient care in the future. The CPG can assist in identifying priority areas for research and informing optimal allocation of resources. Future studies examining the results of CPG implementation may lead to the development of new evidence particularly relevant to clinical practice.

Implementation Tools

Clinical Algorithm

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Management of Pregnancy Work Group. VA/DoD clinical practice guideline for the management of pregnancy. Version 3.0. Washington (DC): Department of Veterans Affairs, Department of Defense; 2018 Mar. 147 p. [237 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2018 Mar

Guideline Developer(s)

Department of Defense - Federal Government Agency [U.S.]

Department of Veterans Affairs - Federal Government Agency [U.S.]

Veterans Health Administration - Federal Government Agency [U.S.]

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United States Government

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Management of Pregnancy Work Group

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Financial Disclosures/Conflicts of Interest

Conflicts of Interest

At the start of this guideline development process and at other key points throughout, the project team was required to submit disclosure statements to reveal any areas of potential conflict of interest (COI) in the past 24 months. Verbal affirmations of no COI were used as necessary during meetings throughout the guideline development process. The project team was also subject to random web-based surveillance (e.g., Centers for Medicare and Medicaid Services open payments or ProPublica).

If a project team member reported a COI (actual or potential), then it was reported to the Office of Evidence Based Practice. It was also discussed with the Pregnancy Clinical Practice Guideline (CPG) Champions in tandem with their review of the evidence and development of recommendations. The Office of Evidence Based Practice and the Pregnancy CPG Champions determined whether or not action, such as restricting participation and/or voting on sections related to the conflict or removal from the Work Group, was necessary. If it was deemed necessary, action to mitigate the COI was taken by the Champions and Office of Evidence Based Practice, based on the level and extent of involvement. No conflicts of interest were identified for the Pregnancy CPG Work Group members or Champions. Disclosure forms are on file with the Department of Veterans Affairs Evidence Based Practice Program office and available upon request.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Department of Veteran Affairs, Department of Defense. VA/DoD clinical practice guideline for management of pregnancy. Washington (DC): Department of Veteran Affairs, Department of Defense; 2009. 163 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Department of Veterans Affairs (VA) Web site .

Availability of Companion Documents

The following are available:

VA/DoD clinical practice guideline for the management of pregnancy. Version 3.0. Clinician summary. Washington (DC): Department of Veterans Affairs, Department of Defense; 2018 Mar. 40 p. Available from the Department of Veterans Affairs (VA) Web site .

VA/DoD clinical practice guideline for the management of pregnancy. Version 3.0. Pocket card. Washington (DC): Department of Veterans Affairs, Department of Defense; 2018 Mar. 10 p. Available from the VA Web site .

Guideline for guidelines. Washington (DC): Department of Veterans Affairs; 2013 Apr 10. 26 p. Available from the VA Web site .

Putting clinical practice guidelines to work in VHA. Washington (DC): Department of Veterans Affairs. 64 p. Available from the VA Web site .

Patient Resources

The following is available:

VA/DoD clinical practice guideline for management of pregnancy. Version 3.0. Patient summary. Washington (DC): Department of Veterans Affairs, Department of Defense; 2018 Mar. 7 p. Available from the Department of Veterans Affairs (VA) Web site .

The My Pregnancy A to Z Journal app is available from the VA Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This summary was completed by ECRI on May 5, 2004. This summary was updated by ECRI Institute on October 3, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium). This summary was updated by ECRI Institute on May 5, 2009, following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium). This NGC summary was updated by ECRI Institute on August 3, 2010. This summary was updated by ECRI Institute on June 5, 2018. The information was verified by the guideline developer on June 11, 2018.

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